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Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Public Health Service (PHS)

National Institutes of Health (NIH)

National Toxicology Program Office

National Toxicology Program; Availability of Technical Report on Toxicology and Carcinogenesis Studies of 4,4'-Diamino-2,2'-Stilbenedisulfonic Acid, Disodium Salt

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DATE: Tuesday, **March** 16, 1993

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of 4,4'-diamino-2,2'-stilbenedisulfonic acid, disodium salt, used in the synthesis of dyes and optical brighteners or fluorescent whitening agents. Fluorescent whitening agents are added to paper, leather, fabrics, plastics, and detergents to enhance colors and whiteness.

Two-year toxicology and carcinogenesis studies were conducted by administering 4,4'-diamino-2,2'-stilbenedisulfonic acid, disodium salt, to groups of 60 rats and 60 mice of each sex in feed for 7 days a week for up to 103 weeks. Rats received feed containing 0, 12,500, or 25,000 ppm and mice received feed containing of 0, 6,250 or 12,500 ppm of the chemical.

Under the conditions of these 2-year feed studies, there was no evidence of carcinogenic activity n1 of 4,4'-diamino-2,2'-stilbenedisulfonic acid, disodium salt, in male or female F344/N rats receiving 12,500 or 25,000 ppm. There was no evidence of carcinogenic activity of 4,4'-diamino-2,2'-stilbenedisulfonic acid, disodium salt, in male or female B6C3F1 mice receiving 6,250 or 12,500 ppm.

n 1 The NTP uses five categories of evidence of carcinogenic activity observed in each animal study: two categories for positive results ("clear evidence" and "some evidence"), one category for uncertain findings ("equivocal evidence"), one category for no observable effect ("no evidence"), and one category for studies that cannot be evaluated because of major flaws ("inadequate study").

The study scientist for this bioassay is Dr. James R. Hailey. Questions or comments about the contents of this Technical Report should be directed to Dr. Hailey at P.O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-0294.

Copies of Toxicology and Carcinogenesis Studies of 4,4'-diamino-2,2'-stilbenedisulfonic Acid, Disodium Salt in F344/N Rats and B6C3F1 Mice (Feed Studies) (TR 412) are available without charge from Central Data Management, NIEHS, MD A0-01, P.O. Box 12233, Research Triangle Park, NC 27709; telephone (919) 541-3419 or (919) 541-0977.

Dated: March 10, 1993.

Kenneth Olden,

Director, National Toxicology Program.

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